

### **REMARKS**

Claims 1, 3, 5-14 and 24-32 are pending. Claims 12-14 are currently withdrawn. Claims 2, 4 and 15-23 were previously cancelled. No new matter is added.

#### **Claim Rejections Under 35 U.S.C. 103**

Claims 1, 3, 7, 11 and 24-32 were rejected under 35 USC 103(a) for being allegedly rendered obvious by U.S. Patent 4,950,227 to Savin et al. (“Savin”) in view of U.S. Patent 6,287,285 to Michal et al. (“Michal”) and further in view of U.S. Patent 5,902,631 to Wang et al. (“Wang”). The Applicants respectfully request reconsideration of this rejection because Savin does not disclose or suggest all the limitations of claim 1, Michal and Wang do not make up for these deficiencies, and Wang expressly teaches away from the proposed modification.

Savin describes a stent delivery system comprising a balloon 14, a stent 16, and two sleeves 16, 18 for holding the stent on the balloon. Savin fails to disclose an adhesion resistant treatment on the outer surface of the balloon (accessible surface) that is in physical communication along the entire length of the stent. Savin does not disclose an adhesion resistant coating that is located between the stent and the balloon, but rather provides that a “lubricating solution” may be between the balloon and the *sleeves*. The sleeves 18 and 20 are not part of the stent 16, and Savin does not state that there is any coating between the stent and the balloon, or even between the stent and the sleeves. Even if the coating between the balloon and the sleeves also results in coating between the balloon and the stent, that coating is only at the ends of the stent—i.e., where the sleeves are—and not “along the entire length” of the stent (or implant) as required by claim 1.

The Examiner admits that Savin “does not disclose a stent having a first implant coating, an adhesion resistant coating covering along the entire length of the implant, an exterior of the second end of the implant delivery device treated with a second adhesion-resistant coating, a second adhesion resistant coating on the accessible surface and a non-adhesive coating made of hydrogel, carbowax or PEO” (Office Action, page 3).

Furthermore, there is no teaching or suggestion to have a lubricating solution in any area other than where the sleeves are located, since the lubricating solution is “to aid in release of stent 16 from the sleeves” (column 4, lines 55-57). Thus, from Savin, there is only motivation for providing a lubricating solution in the area where the sleeves are found. Furthermore, in

Savin, the sleeves can only be on the ends of the stent for the device to work as intended. When the balloon in Savin expands, this “cause[s] the margins of the first and second sleeve to slide axially from over the margins of the stent, thereby simultaneously releasing the ends of the stent from the catheter” (column 2, lines 16-19). Thus, if the sleeves extended along the entire length of the stent, the stent would not be capable of being released at the target site. Therefore, there is no teaching, suggestion, or motivation in Savin to have a lubricating solution on the remaining central section of the stent.

The Examiner states that Wang “discloses that the coating can optionally extend[s] over all of segments 20 and 16 (see col. 3, line 29-36)” (Office Action, page 3). From this, the Examiner concludes that Wang teaches a lubricious coating over an entire balloon and proposes to modify Savin on this basis. Applicants respectfully submit that the conclusion drawn from the Wang reference is incorrect, and, in fact, Wang expressly teaches away from the proposed modification.

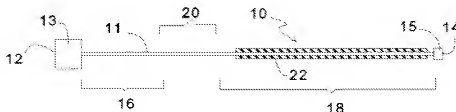
Wang describes a medical device, wherein at least a portion of the in-the-body segment is provided with a lubricious coating. The device 10 may be a guide wire, a catheter, a cannula, a fiber optic device, or the like. The device can optionally be provided with a functional structure 15, such as an inflatable balloon, deployable stent, drug delivery mechanism, or the like, typically at or near the distal end 14. Wang states that “[d]epending on the intended use of such a device, the requirements for lubricity along the surface of the device may vary widely. In the case of balloon catheters, it is desirable for the balloon to have a lubricating portion *and a non-lubricating portion* to avoid the so-called ‘watermelon seed’ problem wherein a balloon which is too lubricious shoots forward on inflation” (col 1, lines 27-32, emphasis added).

In this statement, Wang expressly teaches away from providing a lubricious coating over the entire length of a balloon catheter. This was in fact the conventional wisdom in the art, i.e., that all or at least a portion of the length of a balloon should be *non-lubricating* in order to avoid the balloon slipping or shooting out of position when inflated, the so-called “watermelon seed” problem.

In Wang’s specification, Wang teaches coatings on guide wires, catheters, and the like, but not on a balloon. In Wang’s, Figure 1, reproduced below, Wang separates the device into 5 different areas, namely: (1) control mechanism 13, (2) out-of-body segment 16, (3) a middle

segment 20 which may vary between out-of-body and in-the body positions, (4) in-the-body segment 18, and (5) “functional structure 15, such as an inflatable balloon” (col. 2, lines 48-49).

*Fig. 1*



In discussing the possible locations of the lubricious coatings, Wang specifically omits the functional structure 15. This is consistent with Wang’s statement that it is desirable to avoid the “watermelon seed” problem. In the passage cited by the Examiner, Wang states:

In accordance with the present invention in-the-body segment 18 includes a coated portion 22. Portion 22 may be coextensive with segment 18 or only a fractional length of segment 18. The coating which forms portion 22 may optionally also extend over some or all of segments 20 and 16, however for purposes of this invention only portion 22 is of interest.

(Wang, col. 3, lines 29-35).

Each of the segments that Wang suggests coating—i.e., segments 16, 20 and 18—is separate from the functional structure 15. Wang does not describe or suggest coating the functional structure 15, and nothing in Wang at all suggests coating the entire length of a balloon. In fact, Wang expressly teaches away from coating the entire length of a balloon, by stating that “it is desirable for the balloon to have a lubricating portion *and a non-lubricating portion*” to avoid the “watermelon seed” problem (col 1, lines 27-32, *emphasis added*). Accordingly, Wang expressly teaches away from the modification of Savin as proposed in the Office Action.

For the reasons discussed above, Savin and Wang do not disclose or suggest all of the limitations of claim 1, and all claims that depend therefrom, and Michal does not cure these deficiencies. Thus, the combination of Michal, Savin, and Wang does not disclose all the limitations of claim 1, and all claims which depend therefrom.

**CONCLUSION**

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,  
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